IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

RENEGADE TOBACCO COMPANY, INC., *et al.*	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 3:10-cv-00265-HEH
	)	
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

This memorandum is filed by Plaintiffs Renegade Tobacco Company, Inc.; Alternative Brands, Inc.; Renegade Holdings, Inc. (collectively, "Renegade"), and Seneca-Cayuga Tobacco Company ("Seneca-Cayuga"), by counsel, in support of their Motion for Preliminary Injunction.

INTRODUCTION

Plaintiffs have brought a complaint seeking to prevent the U.S. Food and Drug Administration ("FDA") from enforcing a regulation, 21 C.F.R. § 1140.16(a) ("the Product Name Restriction"), which was adopted by the FDA as a final rule on March 19, 2010, with an effective date of June 22, 2010. *See* 75 Fed. Reg. 13225-13232 (March 19, 2010). As written, the regulation will stop many small cigarette manufacturers from selling cigarettes under well-established brand names if those names also are used on non-tobacco products. For example, a small cigarette manufacturer that sells cigarettes under the name "Tucson" will have to stop using that brand name or face severe civil and criminal penalties, simply because an automaker, Hyundai, decided to sell vehicles under the same name, a decision Hyundai made years *after* Renegade's products were already on the market. That small cigarette manufacturer, a plaintiff in this case, will see its business destroyed.

On the other hand, the big tobacco companies whose cigarette brands dominate the marketplace will be able to continue selling under their brands names *whether or not* any non-tobacco product use the same names. This is because the regulation provides immunity for brand names that were in effect on January 1, 1995, so long as non-tobacco products using the same name were being sold anywhere in the United States on that same date. This immunity protects most if not all of the major brand names now in use by the big tobacco companies.

The practical effect of the regulation, as written, will be to drive the relatively new, small cigarette manufacturers out of business by banning the use of their established brand names (and by effectively preventing them from establishing new brand names), while protecting the big tobacco companies that have long-dominated – and that continue to dominate – the cigarette market in the United States.

The FDA's Announcement of May 4, 2010

When this lawsuit was filed on April 23, 2010, the FDA had taken no action to allay the widespread concerns about the unconstitutional and destructive regulation that is the subject of this litigation. Although the FDA admitted that its regulation was problematic, *see* 75 Fed. Reg. 13225, the agency did nothing to solve any of the problems the regulation caused. Then, on May 4, 2010, the FDA announced a new policy with respect to the *enforcement* – albeit not the *terms* or the *interpretation* – of the regulation; and it is likely that the FDA will argue that its May 4 announcement shields the agency against a preliminary injunction. The argument is misguided.

Superficially, the FDA's announcement may seem to address the concerns raised by the Plaintiffs in seeking a preliminary injunction; however, the FDA's published assurances are wholly illusory. Indeed, the same announcement makes it clear that the FDA is *not bound* by its

assurances, and that the public – including Plaintiffs – are still at risk of seeing their rights violated and their businesses destroyed. Although the bulk of this memorandum was written before the FDA made its announcement, Plaintiffs also address the May 4 announcement. As Plaintiffs will show, the case for a preliminary injunction is now even stronger.

FACTS

The Regulation

The Product Name Restriction, which is at the crux of this case, provides as follows:

> Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

21 C.F.R. § 1140.16(a).

Products that fail to comply with the Product Name Restriction are considered "misbranded" under the Federal Food, Drug, and Cosmetic Act. *See* 21 C.F.R. §1140.1. Misbranded products, in turn, may be seized and destroyed, and severe civil and criminal penalties – including substantial fines and imprisonment – may be imposed on the manufacturers and sellers of such products. *See* 21 U.S.C. §§ 333 and 334.

This is not the first time the FDA has sought to restrict the use of brand names on cigarettes. In 1995, the FDA gave notice of its intent to adopt such a regulation, *see* 60 Fed. Reg. 41314, 41374 (August 11, 1995), and in 1996, the FDA adopted the proposed regulation, *see* 61 Fed. Reg. 44396, 44616 (August 28, 1996) (adopting Final Rule). The 1996 Regulation, 21 C.F.R. § 897.16(a), used exactly the same text found in the 2010 regulation now at issue. The 1996 Regulation (along with many other tobacco-related regulations) was later struck down

when the U.S. Supreme Court decided that the FDA had no authority to regulate tobacco. *See Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

In 2009, Congress adopted new legislation, for the first time giving the FDA authority to regulate tobacco. *See* P.L. 111-31 (June 22, 2009), now codified at 15 U.S.C. §§ 1333 *et seq*. As part of this act, Congress directed the FDA to adopt a regulation "identical in its provisions" to the regulations adopted by the FDA in 1996. *See* 75 Fed. Reg. 13225, 13229 (March 19, 2010). At the same time, however, Congress directed the FDA to "include such modifications to [the 1996 regulations] that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court in *Lorillard Tobacco Co. v. Reilly,* [533 U.S. 525 (2001)]." P.L. 111-31, § 102(a)(2)(E); *see also* 75 Fed. Reg. at 13226.

In *Lorillard*, the Court held that "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information." 533 U.S. at 571. One of the lessons of *Lorillard* is that the marketing of cigarettes constitutes commercial speech that is entitled to protection under the Free Speech Clause of the First Amendment. It is a lesson the FDA chose to ignore.

The Effects of the Regulation

As explained in the Complaint, the Product Name Restriction, as written, will impact small tobacco companies in at least six ways:[1]

First, the Product Name Restriction is not limited to cases where a *single manufacturer* produces both a tobacco product and a non-tobacco product using the same trade or brand name.

[1] These examples apply to companies, such as Plaintiffs, that are not eligible for the 1995 Names-In-Use Exception. *See* discussion *infra* at 6-7.

Instead, a cigarette manufacturer will be forced to abandon use of its trade name if a ***wholly-unrelated*** manufacturer uses that name on a non-tobacco product.

Second, the Product Name Restriction applies regardless whether there is any ***likelihood of confusion*** on the part of consumers.

Third, the Product Name Restriction applies regardless whether the cigarette manufacturer used its trade name first and regardless whether that cigarette manufacturer has a ***trademark registration.***

Fourth, the Product Name Restriction applies regardless whether the tobacco product and the non-tobacco product are sold in the same ***geographic market***.

Fifth, the Product Name Restriction is not limited to names appearing on a readily accessible ***list of non-tobacco products***, such as a list of federally-registered trademarks. Instead, it applies to names appearing on non-tobacco products offered for sale anywhere in the economy. Thus, a cigarette manufacturer has no way of knowing with any assurance that its existing brand name – or a name it contemplates using – complies with the regulation.

Sixth, the Product Name Restriction is not limited to names adopted in the future by tobacco product manufacturers; it also applies to names ***already in use*** when the regulation was adopted on March 19, 2010. Thus, a cigarette manufacturer who has been using a trademarked brand name for many years before the adoption of the regulation will be forced to abandon the name if a non-tobacco manufacturer uses the same name for a non-tobacco product name (as long as the name was not being used on both a tobacco product and a non-tobacco product as of January 1, 1995).

The Product Name Restriction thus not only impinges on the commercial speech of the cigarette manufacturer, it also takes and destroys the cigarette manufacturer's property interests

in its product name, including any trademarks for that name and goodwill associated with that name.

These Effects Impact the Plaintiffs

As explained in the attached Declaration of Michael Mebane and Declaration of Chief Leroy Howard, small cigarette manufacturers – including Plaintiffs – will be harmed by the Product Name Restrictions. Summarized below, those explanations are incorporated by reference.

Renegade

Renegade's principal brand names include "Tucson," "Tracker," and "Barton."[2] Renegade has invested significant funds in developing each of these brand names and accompanying goodwill and has an established property interest in these brand names. Mebane Decl. ¶ 4. Renegade has not marketed any non-tobacco products under these brand names, nor does it intend to market any non-tobacco products under these brand names. *Id.* ¶ 5. Nonetheless, Renegade is subject to the Product Name Restriction and is not eligible for the 1995 Names-In-Use Exemption for any of its principal cigarette brands because none of the foregoing Renegade brand names was being used on a cigarette product on January 1, 1995.

One or more other manufacturers – having no connection with Renegade – now use the names "Tucson," "Tracker" and "Barton" for their non-tobacco products. For example, according to the USPTO: the trademark "Tucson" is used on, *inter alia*, automobiles (Serial No. 78295857); the trademark "Tracker" is used on, *inter alia*, handheld computers used for playing

[2] Renegade Tobacco Company, Inc. holds the following trademarks for these names: "Tucson," Serial No. 76156510, registered September 7, 2004; "Tracker," Serial No. 76525463, registered March 1, 2005; and "Barton," Serial No. 76547561, registered December 4, 2007. Mebane Decl. ¶¶ 6, 9, 11.

bingo (Serial No. 78844526); and the trademark "Barton" is used on, *inter alia*, alcoholic beverages (Serial No. 75699796). *Id.* ¶¶ 8, 10, 12. Thus, effective June 22, 2010, Renegade will be in violation of the Product Name Restriction unless it abandons the Tucson, Tracker and Barton trademarks.

Seneca-Cayuga

The only brand of cigarettes sold by Seneca-Cayuga is "Skydancer."[3] Howard Decl. ¶ 5. Seneca-Cayuga also serves as a contract manufacturer for cigarettes sold under the brand name "Golden Bay." *Id.* ¶ 10. Seneca-Cayuga has invested significant funds in developing the "Skydancer" brand name and accompanying goodwill, and it has an established property interest in this brand name. *Id.* ¶ 5. Seneca-Cayuga has not marketed any non-tobacco products under the Skydancer brand name, nor does it intend to market any non-tobacco products under such brand name. *Id.* ¶ 6. Because the Skydancer brand name was not being used on a cigarette product on January 1, 1995, Seneca-Cayuga is subject to the Product Name Restriction and is not eligible for the 1995 Names-In-Use Exemption for its "Skydancer" cigarette brand.

Additionally, Seneca-Cayuga is aware of another business – wholly-independent of Seneca-Cayuga – that uses and/or has used the name "Skydancer" on a non-tobacco product, namely, inflatable action figures. *Id.* ¶ 9. Other businesses also might choose to use the "Skydancer" name for other non-tobacco, such as kites, various aeronautical products or almost anything else. Seneca-Cayuga would have no legal recourse to prevent a non-tobacco manufacturer from using the "Skydancer" name if the use is not likely to cause confusion or

[3] Seneca-Cayuga holds the registered trademark "Skydancer" (the "Skydancer Mark"), Serial No. 78172235, registered March 21, 2006, for use on, *inter alia*, cigarettes. Howard Decl. ¶ 7.

mistake, or to deceive. Indeed, if the non-tobacco business did not apply for a federal trademark, Seneca-Cayuga might not even know that the name was being used by someone else.

The 1995 Names-In-Use Exception

Part of the problem with the new Product Name Restriction can be traced to a "grandfather" clause contained in the old 1996 FDA regulation. That clause gave certain protections to names in use as of January 1, 1995 – *i.e.* at the beginning of the calendar year when the regulation was first proposed. If the FDA had followed the same approach in its current regulation, it would have used January 1, 2009, as the date for giving "grandfather" clause protection to names in use. Instead, in its new regulation, the FDA leapt all the way back to January 1, 1995 – a date *fourteen years* earlier. Thus, although the new regulation uses the *same text* as the earlier regulation, it does so with a radically *different effect*: it destroys the brand names – and associated goodwill – developed by small cigarette manufacturers in reliance on the Supreme Court's decision in *Brown & Williamson*.

While the Product Name Restriction will have catastrophic effects on small cigarette manufacturers, its impact will be negligible on the largest manufacturers who already control an overwhelming share of the U.S. tobacco market. In 1995, the cigarette market in the United States was dominated by four large tobacco companies: Philip Morris Inc., R.J. Reynolds Tobacco Co., Brown & Williamson Tobacco Corp. and Lorillard Tobacco Co. In 1995, these four companies collectively accounted for 97.8 percent of the cigarette market in the United States. John Maxwell, *Premiums Up,* Tobacco Reporter, March 1996, at 16. Today, these same large tobacco companies collectively account for approximately 90 percent of the cigarette

market in the United States.[4] (The number of these dominant manufacturers was reduced from four to three when Brown & Williamson merged with R.J. Reynolds in July 2004, creating a new parent company, Reynolds American, Inc.).

As reported by the Centers for Disease Control ("CDC"), the six top-selling brands in the United States and their respective market shares are as follows: **Marlboro –** 41.0%; **Newport –** 9.7%; **Camel –** 6.7%; **Doral –** 3.8%; **Basic –** 3.5%; **Winston –** 3.2%. *See* http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/brand_preference/index.htm (reporting data from 2008). These six top-selling brands collectively account for 67.9 percent of the cigarette market in the United States, and they include the three most heavily advertised brands, Marlboro, Newport and Camel. *Id.* Yet, each of these six top-selling brand names were being used on both tobacco and non-tobacco products prior to January 1, 1995, and therefore each is protected by the 1995 Names-In-Use Exception. Thus, *at least* two-thirds of the cigarette market is not subject to the restrictions of the Product Name Restriction.[5] In fact, the majority (and perhaps all) of the cigarette brand names currently used by the three large tobacco companies are protected by the 1995 Names-In-Use Exception, thereby insulating approximately 90 percent of the current cigarette market in the United States from the Product Name Restriction.

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[4] This percentage is drawn from the market share data reported in these manufacturers' annual reports (Form 10-K) to the Securities and Exchange Commission. These reports are available at http://www.sec.gov.

[5] *See, e.g.*, "Marlboro" clothing (Trademark Serial Nos. 73253754, 71494855); "Newport" hip braces (Trademark Serial No. 74350881); "Camel" glassware (Trademark Serial No. 74115594), "Doral" sedatives and sleep aids (Trademark Serial No. 73813871), "Basic" surgical shoe covers (Trademark Serial No. 74491696), and "Winston" automobile tires (Trademark Serial No. 72378552).

The principal effect of the Product Name Restriction will be to protect the large tobacco companies from competition by (a) destroying the ability of the new, small cigarette companies to market their products using their current brand names, (b) preventing the new, smaller cigarette companies from building brand identities using new names, and (c) protecting the ability of the large, pre-1995 tobacco companies to market their major brands. In other words, the Product Name Restriction will assure the large tobacco companies continued dominance in the marketplace, while driving from the marketplace their small competitors.

The FDA's Recognition of Flaws – and Its Flawed Response

When it adopted the Product Name Restriction, the FDA acknowledged, in effect, that the regulation is problematic. As the agency stated: *"FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate."* 75 Fed. Reg. 13225 (emphasis added). At the time the Complaint was filed, the FDA had done nothing to address those concerns. Then, on May 4, 2010, the FDA announced what it termed "Guidance for Industry and FDA Staff: Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco" (the "Guidance"). A copy of the Guidance is attached as **Exhibit A**. In the Guidance, the FDA announced how it "intends to exercise its enforcement discretion concerning 21 C.F.R. 1140.16(a)." According to the FDA, the agency,

> intends… not to commence enforcement actions under this provision for the duration of its consideration [of possible changes to the regulation] where:
>
> (1) The trade or brand name of the cigarette or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or
>
> (2) The first marketing or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the non-tobacco product bearing the same name; provided, however, that the

> tobacco and non-tobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).

Exhibit A.

All of the brands owned by Plaintiffs were registered, or the product was marketed, on or before the date cited in the Guidance, June 22, 2009; however, despite any superficial assurances, the Product Name Restriction remains highly problematic for at least three reasons:

First, there is nothing to prevent the FDA from changing its mind and deciding to enforce 21 CFR § 1140.16(a) even in circumstances where its present "intention" is not to do so. A court date is scheduled only about three weeks away, with the effective date of the regulation occurring about one month later. There is no assurance that, if the FDA changed its mind, there would be enough notice of the change to obtain a timely court date for a motion for a preliminary injunction. Knowing that the FDA could change its mind at any minute, distributors and retailers are unlikely to keep much of Plaintiffs' products on hand.

Second, if the FDA were to change its mind and adopt a new enforcement policy – one harmful to Plaintiffs' interests – there is nothing in the Guidance to state that the FDA would apply the new policy only *prospectively*. That is to say, the wording of the Guidance leaves the FDA free to begin enforcement actions at any time for actions that occurred while the current policy is in effect.

Third, the foregoing concerns would be less troubling were it not for the fact that the Guidance prefaces the apparently helpful language with a sweeping and emphatic disclaimer: *"This guidance…does not create or confer any rights for or on any person and does not operate to bind the FDA or the public."* (Emphasis added.)

In short, any assurances that the FDA may give with one hand, it takes away with the other. It is unreasonable to expect anyone to rely on the Guidance when that very document says

the public *cannot* rely on it. As the Supreme Court recently explained, "the First Amendment protects against the Government; it does not leave us at the mercy of *noblesse oblige*. We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly." *United States v. Stevens*, No. 08-769, 2010 U.S. LEXIS 3478, at *34-*35 (Apr. 20, 2010).

Nor, should the FDA be heard to suggest that the case is now moot. As the Supreme Court has explained, "[t]he test for mootness in cases such as this is a stringent one. Mere voluntary cessation of allegedly illegal conduct does not moot a case; if it did, the courts would be compelled to leave '[the] defendant . . . free to return to his old ways.'" *City of Mesquite v. Aladdin's Castle*, 455 U.S. 283, 289 (1982) (*quoting United States v. W. T. Grant Co.*, 345 U.S. 629, 632 (1953) (internal quotation marks omitted).

In sum, the FDA studiously avoids making any real commitment that it will adhere to its new enforcement policy and, indeed, goes out of its way to make it clear that it can return to its "old ways" whenever it wishes. Only a preliminary injunction can protect the Plaintiffs from the unconstitutional regulation.

REASONS THIS COURT SHOULD ISSUE A PRELIMINARY INJUNCTION

Legal Standard

Under the standard now used in the Fourth Circuit, in order to obtain a preliminary injunction, "[a] plaintiff must establish '[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.' And all four requirements must be satisfied." *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346 (4th

Cir. 2009) (quoting *Winter v. NRDC, Inc.*, 129 S. Ct. 365, 374 (2008)). In this case, each of these requirements is satisfied and a preliminary injunction should be granted.

I. Plaintiffs Are Likely to Succeed on the Merits of their Claims.

Plaintiffs are likely to succeed on the merits, especially since the defects in the Product Name Restriction are so readily apparent. As outlined in the various counts of the Complaint, the regulation runs afoul of several constitutional principles.

A. The Plaintiffs Are Likely to Succeed on Their Claim that the Product Name Restriction Violates the First Amendment.

As an initial matter, it is clear that Plaintiffs' selection and use of brand names to identify and advertise their products constitutes commercial speech. *E.g., San Francisco Arts & Ath. v. United States Olympic Comm.*, 483 U.S. 522, 535 (1987) (holding that the use of the word "Olympic" is to be treated as "commercial speech" when the use is "for the purpose of trade [or] to induce the sale of any goods or services" (internal quotation marks and citation omitted)); *Friedman v. Rogers*, 440 U.S. 1, 11 (1979) (holding that the "use of trade names in connection with optometrical practice . . . is a form of commercial speech").

It also is clear that commercial speech – including tobacco-related commercial speech – is protected by the Free Speech Clause of the First Amendment. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001) ("[S]o long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information."). Moreover, as with any regulation of speech, the government has the burden of proving that its regulation meets the applicable constitutional standard; it is not Plaintiffs' burden to prove that the regulation fails. As the following discussion will show, the government cannot meet its burden in this case and, thus, the Product Name Restriction is unconstitutional.

1. The Regulation Violates the *Central Hudson* Test.

A government regulation of commercial speech is invalid under the First Amendment if the regulation fails to satisfy the four-part test set forth in *Central Hudson Gas Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980).[6] The *Central Hudson* test consists of four parts, requiring a court to ask: (1) whether the speech concerns lawful activity and whether the speech is misleading; (2) whether the governmental interest served by restricting the speech is substantial; (3) whether the speech restriction directly and materially advances the asserted governmental interest; and (4) whether the speech restriction is more extensive than necessary to serve the asserted governmental interest. *See Greater New Orleans Broadcasting Assoc. v. United States*, 527 U.S. 173, 174 (1999) (applying *Central Hudson* test).

a. Plaintiffs' Brand Names Are Lawful and Not Misleading.

Plaintiffs' selection and use of brand names to identify and advertise their products concerns a lawful activity (the manufacture and sale of tobacco products). Furthermore, Plaintiffs' use of their brand names is not misleading, nor does the Product Name Restriction require that a brand name be misleading in order for that regulation to apply. Given the lawfulness of the activity and the lack of misleading speech, the burden is on the government to "identify[] a substantial interest and justify[] the challenged restriction." *Greater New Orleans*, 527 U.S. at 174 (applying *Central Hudson* test).

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[6] There has been some suggestion by one or more members of the Supreme Court that strict scrutiny, rather than the *Central Hudson* test, should be used to judge restrictions on commercial speech. Although Plaintiffs agree with that position, it is not necessary for the Court to apply strict scrutiny in order tor the Plaintiffs to prevail. Thus, this portion of the discussion will focus on showing why the regulation at issue fails to satisfy *Central Hudson*.

b. The FDA Lacks a "Substantial Interest" in Preventing Smoking by *Adults.*

The government has not yet identified precisely what interest it will assert in defense of the Product Name Restriction. Based on the stated purpose of the original regulation, it is likely the FDA will say that its interest is in preventing smoking by *minors*. *See* 60 Fed. Reg. 41,314, 41,315 (Aug. 11, 1995). If so, Plaintiffs will agree that such an interest qualifies as substantial. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564 (2001) ("State's interest in preventing underage tobacco use is substantial…"). It is not enough, however, that government has a "substantive interest" in the abstract. Instead, it must have a substantial interest in regulating the speech at issue.

In *Psinet, Inc. v. Chapman*, 362 F.3d 227 (4th Cir. 2004), the Fourth Circuit Court of Appeals applied these principles when it struck down an attempt by the Commonwealth of Virginia to regulate sexually explicit internet content. In that case, the Commonwealth tried to justify its restrictions on grounds that it only sought to restrict the availability of such content to minors. The court held that even though the *intent* of the law may have been to prevent access by minors, the *effect* was to create a "blanket prohibition of adult commercial speech." *Id.* at 238. This, the court held, "violates the First Amendment." *Id.* The court reasoned that "[w]hen the government defends a regulation of speech as a means to redress past harms or prevent anticipated harms, it must do more than simply 'posit the existence of the disease sought to be cured.'" *Id.* at 238 (quoting *Turner Broad. Sys. v. F.C.C.*, 512 U.S. 622, 664 (1994)). In other words, it is the government's interest in the speech *actually targeted* by the regulation that matters, not its interest in another category of speech that the government claims it *intended to target*.

In this case, though the government claims it intends to target the marketing of tobacco products to minors, the Product Name Restriction actually targets the marketing of tobacco products to all customers. As a result, it is speech to adults, not children, that is most affected by the regulation. This is because the selection of brand names and their display in cigarette packages is speech seen overwhelmingly – though not always exclusively – by adults, not children. There is no substantial interest in preventing the use of cigarettes – a lawful product – by ***adults*** so as to justify such regulations on such commercial speech. As the Supreme Court has explained: "[T]obacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products." *Lorillard*, 533 U.S. at 564. There is nothing untruthful about a manufacturer applying to a cigarette package a trade name registered by the manufacturer with the U.S. Patent and Trademark Office and used by the manufacturer to identify the product.

The parallels between these restrictions on cigarette advertising and overbroad restrictions on indecent speech, which have been struck down by the Supreme Court, could not be clearer. Indeed, the Court, itself, has compared sweeping restrictions on cigarette advertising to overly-aggressive restrictions on "indecent speech," noting that "the governmental interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech addressed to adults." *Id.* (quoting *Reno v. ACLU*, 521 U.S. 844, 875 (1997)). Thus, "[a]s the State protects *children* from tobacco advertisements, *tobacco manufacturers and retailers and their adult consumers still have a protected interest in communication*." *Id.* (emphasis added). In short, the fact that tobacco is a regulated commodity does not give the government *carte blanche* to impose whatever regulations it may wish.

c. The Regulation Does Not "Directly and Materially Advance" the Goal of Preventing Underage Smoking.

On a related note, even if the government asserts that its interest in regulating the speech at issue is solely preventing underage tobacco use, the regulation is also invalid because does not "directly and materially advance" that interest, as required by *Central Hudson*. Preventing underage tobacco use is, to be sure, a substantial government interest, *Lorillard*, 533 U.S. at 564; however, even where "the Government's asserted interests are important in the abstract [that] does not mean… that the [regulation] will *in fact* advance those interests." *PSINet Inc. v. Chapman*, 167 F. Supp. 2d 878, 884 (W.D. Va. 2001) (emphasis added) (quoting *Turner Broad. Sys. v. F.C.C.*, 512 U.S. 622, 664 (1994)). When the FDA comes to court, it will have the burden of proving that the regulation will substantially deter smoking by minors. This it cannot do, because the regulation is underinclusive.

More than 90 percent of the cigarettes sold in the United States are exempt from the Product Name Restriction. *See* discussion *supra* at 8-9. Indeed, it is well-established that young people prefer brands popularized by the large tobacco companies, and those brands are protected by the 1995 Names-In-Use Exception. According to the 2005 National Survey on Drug Use and Health, conducted by a federal agency, the Substance Abuse and Mental Health Services Administration of the Department of Health and Human Services, 91 percent of youths ages 12 to 17 preferred cigarettes manufactured by the largest three tobacco companies, with 82 percent of youths preferring just three brands: 48 percent favoring Marlboro (manufactured by Philip Morris Inc.); 23 percent favoring Newport (manufactured by Lorillard Tobacco Co.); and 10 percent favoring Camel (manufactured by Reynolds American, Inc.). *See* National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, Office of Applied Studies (2005), *data available at* http://www.oas.samhsa.gov/nsduh/

2k5nsduh/tabs/Sect7peTabs58to67.pdf. In other words, the youth cigarette market is "served" almost exclusively by the three largest cigarette manufacturers, with each of those manufacturers having at least one of its brands as its brand of choice for young people. It is not surprising that this is so. Each of these large manufacturers has been convicted in federal court of RICO violations for deliberately marketing its products to young people and then fraudulently concealing its youth-oriented marketing scheme. *United States v. Philip Morris USA, Inc*., 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in part, vacated in part and remanded*, 566 F.3d 1095 (D.C. Cir. 2009), *petition for cert. filed* 78 U.S.L.W. 3501 (U.S. Feb. 19, 2010) (No. 09-976).

Perversely, however, the FDA has given these youthful brands-of-choice immunity from its regulation, focusing its fire instead on a category of brands that young people rarely smoke and on cigarette manufacturers that have never been charged – must less convicted – of doing anything unlawful. Such a topsy-turvy regulatory scheme does not "directly advance" the goal of discouraging youth smoking.

The underinclusiveness of the Product Name Restriction refutes any claim that the regulation "directly and materially advances" any interest in preventing smoking by minors. As the Supreme Court has explained, "a classification that is substantially … *underinclusive* tends to undercut the governmental claim that the classification serves legitimate political ends." *Cabell v. Chavez-Salido*, 454 U.S. 432, 440 (1982) (emphasis added); *accord Carey v. Brown*, 447 U.S. 455, 465 (1980) (holding that "a statute's over- and under-inclusiveness 'undermine [the] claim that the prohibition … can be justified by reference to the State's interest'"). Or, as the Fourth Circuit has explained, "the Supreme Court has found an underinclusive restriction of speech to be impermissible . . . where the underinclusiveness is so severe that it "raises serious doubts" about whether the government is actually serving the interests it invokes." *National Fed'n of the*

Blind v. FTC, 420 F.3d 331, 346 (4th Cir. Md. 2005) (citing *Florida Star v. B.J.F.*, 491 U.S. 524, 540, (1989); *Cincinnati v. Discovery Network*, 507 U.S. 410, 424-26 n.5 (1993)). In other words, the goal of preventing underage smoking may be legitimate, but the underinclusiveness of the Product Name Restriction means that the regulation is not actually serving that goal. Thus, the regulation fails to meet the third prong of the *Central Hudson* test.

d. The Regulation is "More Extensive than is Necessary."

The Product Name Restriction is "more extensive than is necessary to serve [the government's] interest" in preventing underage smoking. Thus, the regulation fails to meet the final prong of *Central Hudson. See* 447 U.S. at 566.

The regulation fails this prong for two fundamental reasons. First, there are avenues by which the government may pursue its goal without ever touching the brand name choices of cigarette manufacturers. Second, even if *some sort* of brand name regulation were required, the restrictions contained in the Product Name Restriction are breathtaking in their scope. A narrower regulation would do the job just as well.

First, there are many methods by which the government may prevent underage tobacco use, and many of those methods are already in place or were adopted by the FDA as part of the same regulatory package that contains the Product Name Restriction. For example:

- **Sales to minors:** Cigarettes may not be sold to anyone younger than 18 years of age; and retailers must examine a photographic identification bearing the person's birth date to verify that any person purchasing cigarettes or smokeless tobacco is at least 18 years old. Verification is not required for purchasers who are over the age of 26. 21 C.F.R. § 1140.14

- **Vending Machines:** Cigarettes may not be sold through vending machines or self-service displays, except in facilities where persons under the age of 18 are prohibited from entering. 21 C.F.R. § 1140.16

- **Magazine advertising:** Advertisements in teen magazines or similar publications for cigarettes may not use color, but rather must use black text on a white background. 21 C.F.R. § 1140.32

- **Radio and television advertising:** Audio advertisements for cigarettes or smokeless tobacco may not include music or sound effects; and video advertisements for cigarettes or smokeless tobacco may not use color, but rather are limited to static black text on a white background. *Id.*

- **Point of sale advertising:** Labeling and advertisements for cigarettes or smokeless tobacco may not use color, but rather must use black text on a white background. *Id.*

Given this array of regulations, many of them new, it is unreasonable for the FDA to impinge upon the First Amendment by interfering with brand names. Once the other regulations have been in effect for a reasonable period – and their effects assessed – it may or may not be reasonable to adopt additional regulations. But, certainly for now, the FDA cannot show that the Product Name Restriction is no more extensive than is necessary; indeed, it cannot even show that it is necessary at all.

Second, even if there were some current need for the FDA to interfere with brand names, the Product Name Restriction is far too broad. When the FDA first adopted a product name restriction in 1996, it explained that it was concerned about the possibility of a cigarette manufacturer deliberately using the same name as a popular, youth-oriented product. As the FDA-explained: "If a firm could use a popular nontobacco product trade name and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people." 61 Fed. Reg. at 44,444. As examples of such marketing, the FDA mentioned cigarettes named "Harley-Davidson" (also a motorcycle), "Cartier," (a line of jewelry) and "Yves St Laurent's Ritz" (combining the names of a fashion designer and a high-end hotel chain) *Id.* The FDA speculated that such a marketing strategy would promote smoking of that brand by young people and that the Product Name Restriction would prevent that marketing strategy from being used. *Id.*[7] Yet, even if such cigarette marketing strategies were effective in reaching young people (and there is no evidence that they are) the regulation is more extensive than necessary to deter such marketing strategies. Thus, the Product Name Restriction violates the final prong of Central Hudson. Indeed, the regulation is excessive in at least three ways.

First, where the *cigarette manufacturer uses* the brand name *first*, that manufacturer clearly is not trying to take advantage of the image associated with a pre-existing, non-tobacco product. Yet, the Product Name Restriction applies regardless of who used the name first. In the

[7] The FDA cited no evidence that a tobacco product bearing a non-tobacco name would be especially appealing to young people. Indeed, the evidence showed that the brands cited by the FDA either only represented a very small market share, or were not sold in the United States. Moreover, the government's own studies show that young smokers overwhelmingly prefer specific brands of each of the major tobacco companies: Marlboro, Newport and Camel. *See supra* at 17-18.

case at bar, for example, Renegade used and trademarked the name "Tucson" for its cigarettes years before Hyundai applied that same name to one of its vehicles. Even so, the fact that Hyundai later decided to use that name is enough to force Renegade to abandon its brand.

Second, the regulation applies whether or not the non-tobacco product is popular among adolescents. For example, "Northern" is a brand of toilet paper, hardly a glamour product. Yet, because there is a brand of toilet paper named "Northern," no tobacco manufacturer can use that name on its cigarettes. The same is true for the brands used by Renegade and Seneca-Cayuga. While various non-tobacco products use and/or have used the names "Tucson," "Tracker," "Barton," and "Skydancer," Plaintiffs are unaware of any products using those names that would appeal to adolescents.

Third, if a youth-oriented, non-tobacco product is so widely popular as to tempt a cigarette manufacturer to use the same brand name on its cigarettes, the name at issue almost certainly will be trademarked by the manufacturer of that non-tobacco product. Yet, the regulation is not limited to names that are the subject of live trademarks. Instead, the regulation applies to any product in the national economy, whether trademarked or not.

In sum, if the FDA wishes to prevent a cigarette manufacturer from deliberately using the same name as a popular youth-oriented product – and, if government interest in achieving that goal can qualify as "substantial" – the agency can achieve that goal by a regulation far narrower than the one at issue here. For this reason, too, the Product Name Restriction fails to meet the *Central Hudson* test and must be struck down as unconstitutional.

2. The Regulation Is Discriminatory and It Fails Strict Scrutiny

Even if the Product Name Restriction were to meet the *Central Hudson* test, it still would be invalid because it fails to meet other First Amendment tests that are applicable to this case.

Because of the 1995 Names-In-Use Exception, the regulation at issue *discriminates* based on the identity of the speaker and/or the content of the message and, thus, it must be evaluated under strict scrutiny. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 577 (2001) ("[C]ontent-discriminatory regulation [of commercial speech] – like all other content-based regulation of speech – must be subjected to strict scrutiny."); *Citizens United v. FEC*, 130 S. Ct. 876, 900 (2010) (corporations and other associations are entitled to same protections as natural persons under the First Amendment). That is to say, the FDA must show that it has a compelling interest that is advanced by the discrimination, and that the discriminatory provision is narrowly tailored to advance that interest.

The discrimination is clear. By disfavoring brand names adopted after January 1, 1995, the regulation *disfavors* the cigarette manufacturers who began their businesses after that date. The regulation likewise creates a favored category of speech – a class of cigarette brand names – that are favored by being immunized against the same prohibition to which other cigarette brand names are subjected.

The government probably does have an interest – indeed, a compelling one – in providing some sort of grandfather clause for brand names that were trademarked and/or in use at the time the FDA promulgated the regulation in *March 2010* (and/or when Congress called for such regulations in 2009). Not to provide such grandfather clause protection to pre-existing brands would run afoul of various constitutional protections, including the Takings Clause. But there is no legitimate interest – and certainly no compelling interest – in reaching back to *1995* and using *that year* to decide who is protected and who is not. Such discrimination is wholly irrational. Indeed, the FDA has announced its intention to *change* the grandfather date to some unspecified (presumably later) year. Exhibit A. Unfortunately, the change will not come quickly enough to

prevent the regulation from going into effect in its current, flawed form. Even so, the fact that the FDA has acknowledged that the regulation is problematic and that it will move to change the date – albeit lethargically – belies any claim that there is a compelling interest for the discriminatory treatment now caused by the 1995 Names-In-Use Exception.

B. The Regulation Is Void for Vagueness.

Separate and apart from its other constitutional defects, the Product Name Restriction is void for vagueness. The void-for-vagueness doctrine is an outgrowth of the Due Process Clause of the Fifth Amendment. A statute is unconstitutionally vague if it "fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *United States v. Williams*, 553 U.S. 285, 304 (2008). In cases implicating the First Amendment, a statute also may is considered vague and overbroad if "it is unclear whether it regulates a substantial amount of protected speech." *Id.* In this case, the vagueness of the Product Name Restriction violates both the First Amendment and the Due Process Clause of the Fifth Amendment.

The regulation is unduly vague because a cigarette manufacturer cannot know with reasonable certainty that a name it selects will be lawful. When it originally adopted the Product Name Restriction in 1996, the FDA admitted, in effect, that its regulation was unreasonably vague:

> It would be unreasonable for the regulation to encompass all possible nontobacco product trade names, regardless of their nationality *or* whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that a name was not used elsewhere.

61 Fed. Reg. at 44,445 (emphasis added). In response to this concern, the FDA addressed the *first part* of the problem, but not the *second*. It limited the sweep of the regulation to names in use in the *United States*, but it did not limit the regulation to names that are *trademarked*. As a

result, a cigarette manufacturer will violate the regulation if it uses the same name as the non-trademarked name of a non-tobacco product anywhere in the United States. *As the FDA admitted in 1996, there is no way for the manufacturer to be sure that the name it chooses will be lawful.* The manufacturer can only guess. If it guesses wrong and the FDA finds out about it, the manufacturer will then be subject to civil and criminal penalties, plus the loss of its monetary investment in that name and the goodwill the name has accumulated.

Even standing alone, this defect would make the regulation void for vagueness; however, the regulation is vague in other ways, too. For example, key terms in the regulation at issue are undefined – and its application in certain situations is unclear – leaving cigarette manufacturers to guess at their meaning. Among the ambiguous terms are the following:

- **"Product" –** The term "non-tobacco product" may include those goods which, like cigarettes, are tangible in nature. But what about intangibles, and what about services? For example, are restaurant names included? What about hotels? In Anchorage, Alaska, there is a hotel named "Captain Cook." *See* http://www.captaincook.com. Does that mean that it would be illegal to manufacture cigarettes named after the famous explorer? A "person of ordinary intelligence" probably would not consider a hotel a "product." However, one of the examples cited by the FDA of cigarettes names adopting the name of a glamour product included the word, "Ritz." 61 Fed. Reg. at 44,444. Does the FDA intend to include hotel and restaurant names in the regulation? Nobody knows.

- **"Name" –** The gist of the regulation is that it is unlawful to use a brand name on a cigarette if that name is used on a non-tobacco product. But when are two names close

enough to be treated as the same for purposes of the regulation? "Tucson" cigarettes and "Tucson" vehicles clearly use the same name, but what about compound names? For example, would "Tucson Gold" be close enough to "Tucson" to fall under the regulation? And, what if the full brand name were not just "Tucson" but were changed to something like "Tucson Full Flavor?" And, what about plurals, possessives and idiosyncratic spellings? Is "Tracker" close enough to "Trackers" or "Tracker's" or "Traker"" to fall under the regulation? The regulation gives no clue.

- **Other Issues –** The regulation may apply when a manufacturer is *currently* manufacturing and selling non-tobacco products under a particular name, but what happens if that manufacturer discontinues production? The product may continue to be sold on the secondary market, including through surplus stores, online auction sites like E-bay, antique stores and flea markets. Is it still the name "of" a "non-tobacco product" when the product is still being sold in the marketplace, but is no longer being made? And, do such secondary sales count for purposes of the Names-In-Use Exception?

These are important questions for any manufacturer deciding whether to continue an existing brand or to try to start a new one. Yet, given the vagueness of the regulation, manufacturers can only guess at the answers. If they read the regulation too narrowly, they will expose themselves to fines and imprisonment. Yet, if they read the regulation too broadly, they will abolish their brand names, fail to adopt available new ones and ruin their businesses unnecessarily. Moreover, the regulation provides no guidance as to what is a right or wrong answer. It leaves this determination up to the FDA. This is precisely the sort of vagueness that

the constitution condemns, especially where the First Amendment is concerned. *See United States v. Stevens*, No. 08-769, 2010 U.S. LEXIS 3478, at *34-*35 (Apr. 20, 2010); *see also Hill v. Colorado*, 530 U.S. 703, 732 (2000) (regulation is void for vagueness if it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits," and/or "authorizes or even encourages arbitrary and discriminatory enforcement").

C. The Regulation Violates Plaintiffs' Right to Equal Protection under the Due Process Clause.

The Due Process Clause of the Fifth Amendment contains an equal protection component applicable against the federal government and equivalent to the protections applicable against the States under the Equal Protection Clause of the Fourteenth Amendment. *See Bolling v. Sharpe*, 347 U.S. 497, 499 (1954); *Buckley v. Valeoa*, 424 U.S. 1, 93 (1976) (*per curiam*). The Product Name Restriction provides unequal treatment in that it establishes different rules for different cigarette manufacturers depending whether their cigarette brand names (and the names of non-tobacco products) were in use on January 1, 1995. For the same reasons that the regulation constitutes impermissible discrimination and fails to pass strict scrutiny under the First Amendment, as discussed *supra* at 22-23, it also violates the equal protection component of the Due Process Clause of the Fifth Amendment.

D. The Product Name Restriction Destroys Plaintiffs' Property Interests Without Authorization and Without Due Process of Law.

The Product Name Restriction also violates Plaintiffs' due process rights because in enacting the regulation, the FDA overstepped the authority granted to it by Congress. When told to adopt a regulation "identical in its provision" to the regulation introduced in 1996, 75 Fed. Reg. at 13229, the FDA adopted a regulation identical in language, but dramatically different in results. The earlier regulation protected names in use as of January 1, 1995 – *i.e.* at the

beginning of the calendar year when the regulation was first proposed. Rather than following this approach in its current regulation – which would have meant using January 1, 2009, as the date for giving "grandfather" clause protection to names in use – the FDA again referenced January 1, 1995 – a date *fourteen years* earlier. This was a radically different result from the one intended by Congress. The FDA's adoption of this interpretation was *ultra vires*, and its effect is to destroy Plaintiffs' valuable property rights without authorization by Congress and without due process of law.

E. The May 4, 2010 "Guidance" Issued by the FDA Underscores the Unconstitutional Nature of the Product Name Restriction.

In the "Guidance" issued on May 4, 2010, the FDA claims that it "intends to exercise its enforcement discretion concerning 21 CFR 1140.16(a) not to commence enforcement actions under this provision for the duration of its consideration . . ." of how it may modify the Product Name Restriction. Exhibit A. This promise to "exercise discretion" does nothing to mitigate the unconstitutionality of the regulation.

A similar issue arose in *United States v. Stevens*, No. 08-769, 2010 U.S. LEXIS 3478 (Apr. 20, 2010). In that case, the government sought to defend a statute that banned creation, sale or possession of any "depiction of animal cruelty." Recognizing that the regulation was facially overbroad, because it would potential implicate hunting videos, documentaries, and other similar depictions, the government claimed that it would exercise "prosecutorial discretion" to reach only depictions of "'extreme' cruelty." *Id.* at *34. The Court held that the government could not make an unconstitutional statute or regulation constitutional simply by promising to exercise discretion in enforcement, explaining that "the First Amendment protects against the Government; it does not leave us at the mercy of *noblesse oblige*. We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly." *Id.* at

*35. The Court held: "The Government's assurance that it will apply [a statute] far more restrictively than its language provides is pertinent only as an implicit acknowledgment of the potential constitutional problems with a more natural reading." *Id.* In the case at bar, the FDA's announcement that it will "exercise discretion" should be read in the same way: it highlights rather than mitigates the regulation's failure to pass constitutional muster.

For all of the foregoing reasons, the Product Name Restriction is invalid both on its face and as applied to Plaintiffs and their brands. While Plaintiffs are almost certain to prevail on these arguments at a trial on the merits, they need not show such certainty in order to obtain a preliminary injunction. Under the first prong of *Winter*, Plaintiffs need only show that they are "likely" to prevail on the merits. That standard has surely been met.

II. Plaintiffs Are Likely to Suffer Irreparable Harm if an Injunction Is Not Granted.

The second prong of the *Winter* test focuses on the likelihood that the party seeking an injunction will suffer irreparable harm if the injunction is not granted. The prevention of irreparable harm is one of the primary purposes of a preliminary injunction. *Sun Microsystems, Inc. v. Microsoft Corp. (In re Microsoft Corp. Antitrust Litig.)*, 333 F.3d 517, 525 (4th Cir. 2003) ("The traditional office of a preliminary injunction is to protect the status quo and to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability to render a meaningful judgment on the merits."). In this case, Plaintiffs face three types of harms if the FDA enforces the Product Name Restriction: (1) a loss of trademark rights; (2) a deprivation of First Amendment rights; and (3) destruction of their businesses. Each of these types of harms Plaintiffs is considered irreparable *as a matter of law.* Moreover, each of these harms is not only likely; it is certain.

A. A Loss of Trademark Rights Constitutes Irreparable Harm.

First, it is well-settled that a loss of trademark rights constitutes irreparable harm. In trademark lawsuits, once a party makes a *prima facia* showing of trademark infringement, that party is entitled to a presumption of irreparable harm. *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 273 (4th Cir. 2002) ("In Lanham Act cases involving trademark infringement, a presumption of irreparable injury is generally applied once the plaintiff has demonstrated a likelihood of confusion, the key element in an infringement case."). This is because it can be difficult, if not impossible, to quantify the loss of sales and damage to goodwill that is attributable to the diminution of a trademark. *Black & Decker (U.S.) Inc. v. Pro-Tech Power Inc.*, 26 F. Supp. 2d 834, 862 (E.D. Va. 1998); *see also JTH Tax, Inc. v. H&R Block Eastern Tax Servs., Inc.*, 128 F. Supp. 2d 926, 948 (E.D. Va. 2001) ("[A] demonstration that the competitor's advertising tends to mislead consumers satisfies the [Lanham] Act's irreparable harm requirement."), *aff'd in part, vacated in part, and remanded*, 28 Fed. Appx. 207 (4th Cir. 2002).

If the mere *infringement* of a trademark is enough to establish irreparable harm, then certainly the *destruction* of a trademark also constitutes irreparable harm. In this case, the Product Name Restriction will extinguish the trademark rights of Renegade in its Tucson, Tracker and Barton brands and the trademark rights of Seneca-Cayuga in its Skydancer brand. Even if Renegade and Seneca-Cayuga were able to establish new brand names – a highly doubtful prospect, see Mebane Decl. ¶ 21; Howard Decl. ¶ 16 – it would be impossible to quantify the loss of sales and customer goodwill Plaintiffs would experience before these new brands could be brought to market. Under these circumstances, the harm to Plaintiffs due to their loss of trademark rights is irreparable.

B. A Deprivation of First Amendment Rights Constitutes Irreparable Harm.

Second, Plaintiffs' use of their brand names constitutes commercial speech protected by the First Amendment. *See Central Hudson*, 447 U.S. at 566 (if commercial speech concerns lawful activity and is not misleading, it is covered by the First Amendment). As explained above, the FDA's Product Name Restriction violates Plaintiffs' First Amendment rights. *See supra* at 14-24. This violation of Plaintiffs' First Amendment rights constitutes irreparable injury. As this Court stated in *Stuart Circle Parish v. Board of Zoning Appeals*, 946 F. Supp. 1225 (E.D. Va. 1996), "it is clear that 'violations of First Amendment rights constitute *per se* irreparable injury.'" *Id.* at 1235 (citing *J. Doe v. Shenandoah County School Bd.*, 737 F. Supp. 913, 916 (W.D. Va. 1990)). "This is true even where the impairment exists for only a minimal period of time." *J. Doe*, 737 F. Supp. at 916. Indeed, "the denial of First Amendment freedoms *even for a day* inflicts irreparable injury." *Id.* (quoting *Int'l Soc. for Krishna Consciousness v. Hays*, 438 F. Supp. 1077, 1081 (S.D. Fla. 1977)) (emphasis added). Plaintiffs have shown that the FDA's Product Name Restriction regulation violates their First Amendment commercial speech rights. This showing is all that is necessary to establish irreparable harm.

C. The Destruction of Plaintiffs' Businesses Constitutes Irreparable Harm.

Third, enforcement of the Product Name Restriction will force Renegade and Seneca-Cayuga to stop doing business. The inability to sell Renegade's brands beginning June 22, 2010, will cause a negative cash balance by not later than August 2010. Mebane Decl. ¶ 20. Additionally, Renegade will face claims against it of approximately $3.5 million for goods which will be deemed "misbranded" under the Product Name Restriction, and therefore cannot legally be sold. *Id.* Renegade also will be forced to write-off of approximately $1.2 million in finished goods and raw materials, which currently are listed as assets of Renegade. *Id.* The combination

of these factors will force Renegade to stop doing business and close its doors. *Id.* Seneca-Cayuga, too, faces destruction if the Product Name Restriction goes into effect. This is because, if it cannot be established that non-tobacco products named SkyDancer are no longer being sold, then Seneca-Cayuga will have to shut down its business or risk prosecution as well as both civil and criminal penalties. Howard Decl. ¶ 14.

The U.S. Court of Appeals for the Fourth Circuit has stated, "It is well-settled that harm to a company's ability to continue its business and preserve its existence is irreparable." *Federal Leasing, Inc. v. Suburban Trust Co.*, 650 F.2d 495, 500 (4th Cir. 1981). This is because even if the Court somehow were able to *partially* measure the damage caused by the destruction of a business in dollars, "[t]he right to continue a business is not measurable *entirely* in monetary terms; the [owners of the company] want to sell [products], not to live on the income from a damages award." *Id.* (citing *Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197, 1205 (2d Cir. 1970)) (emphasis added).[8]

D. The May 4, 2010 FDA "Guidance" Does Not Prevent Irreparable Harm.

In its May 4, 2010 Guidance, the FDA made clear that its announcement "does not create or confer any rights for or on any person and does not operate to bind FDA or the public." Exhibit A. The Guidance depends entirely on the "discretion" of the FDA and its duration is unknown and subject to revocation at any time by the FDA. *Id.* The distributors to which Plaintiffs' sell their products and the retailers who market these products to the public will be

[8] Indeed, even if one or both Plaintiffs were able to survive the damaging blow the FDA proposes to deal them, they still would suffer irreparable harm. Where damage to a company "endangers its relations with customers and investors, the good will built up by a heretofore successful enterprise; such damage is 'incalculable not incalculably great or small, just incalculable.'" *Federal Leasing*, 650 F.2d at 500 (quoting *Blackwelder Furniture Co. of Statesville v. Selig Manufacturing Co.*, 550 F.2d 189, 197 (4th Cir. 1977)).

unwilling to rely on the Guidance in making investment decisions given these broad caveats. Mebane Dec. ¶ 35. These distributors and retailers know that, if the FDA reverses its position, any of Plaintitffs' cigarettes that they then have on hand will deemed "misbranded" and will be unsellable. Therefore, rather than invest in substantial inventories of cigarette brands that may run afoul of the Product Name Restriction as currently written, distributors and retailers instead will keep on hand, at most, only small quantities of these cigarettes, while stocking up, instead, on cigarettes from the largest manufacturers that are not subject to the Product Name Restriction, as currently written. *Id.* ¶ 36. This caution on the part of distributors and retailers will result in lost sales, lost market share and loss of goodwill by Plaintiffs and other small cigarette manufacturers. For the small manufacturers like Renegade and Seneca-Cayuga, this also will result in large quantities of current product and packaging that cannot be sold. Finally, due to the uncertainty created by the caveats in the FDA's guidance, Plaintiffs and other small manufacturers will be unable as a practical matter to invest in additional equipment, hire additional employees or attract additional investment. *Id.* ¶ 37. In short, while enforcement of the Product Name Restriction as originally written is a sentence to a quick death, the Product Name Restriction as modified by the Guidance is a sentence to a slow death. Each ultimately will lead to the death of Plaintiffs' businesses. Such harm is irreparable.

Each of the types of harms faced by Plaintiffs – extinguishment of trademark rights, violation of First Amendment rights and destruction of their businesses – has been recognized as irreparable as a matter of law. The FDA's May 4 Guidance does not mitigate these harms. Plaintiffs therefore have satisfied the second prong of the *Winter* test.

III. The Balance of the Equities Tips in Plaintiffs' Favor.

The balancing of equities is largely a balancing of harms, comparing the irreparable harm that would occur to Plaintiffs without an injunction to any harm that Defendants would suffer if an injunction is issued. *See, e.g.*, *Allegra Network LLC v. Reeder*, No. 1:09-cv-912, 2009 U.S. Dist. LEXIS 103688, at *10 (E.D. Va. Nov. 4, 2009) ("The balance of the equities favors a preliminary injunction as there has been no evidence that Defendants will suffer irreparable harm. . . ."); *Quesenberry v. Volvo Group N. Am., Inc.*, No. 1:09cv00022, 2009 U.S. Dist. LEXIS 22468, at *52 (W.D. Va. Mar. 10, 2009) (balancing the equities and concluding, "that the harm suffered by the plaintiffs should the injunctive relief be denied far outweighs the harm to the defendants by the grant of such relief."); *Safeway Inc. v. CESC Plaza Ltd. P'ship*, 261 F. Supp. 2d 439, 472 (E.D. Va. 2003) (courts considering the balance of the equities take into account, "at least in part, [the] balance of the hardships imposed on the defendant if the injunction is granted versus the hardships imposed on the plaintiff is the injunction is denied.").

A. The Harm to Plaintiffs Is Significant and Irreparable.

In this case, the balance of the equities clearly tips in favor of Renegade and Seneca-Cayuga and against the FDA. As the Plaintiffs have explained, the regulation at issue will cause them great and irreparable harm, resulting in the destruction of Plaintiffs' products, closure of Plaintiffs' businesses and the termination of Plaintiffs' employees. On the other hand, the regulation does not advance the FDA's purported goal of preventing smoking by minors. *See supra* at 17-19. Moreover, there are numerous ways in which the FDA could pursue its goal without imposing on Plaintiffs the substantial, immediate and irreparable harms that the Product Name Restriction will cause. *See supra* at 19-22 (describing other avenues open to the FDA). Thus, the balance of equities clearly tips in favor of Plaintiffs.

B. The Harm to the FDA Is Minimal and Traditional Equitable Factors Favor Plaintiffs.

The equities in favor of an injunction are further enhanced by the FDA's lackadaisical attitude toward the regulation at issue. Congress enacted the underlying statutory basis for the regulation on June 22, 2009 – nearly a year ago. That legislation excused the FDA from the notice and comment period that regulatory actions normally require. 75 Fed. Reg. at 13229 ("Under section 102(a)(1)(B) [of the Tobacco Control Act], the rule issued under this section is, 'deemed to be in compliance with all applicable provisions of chapter 5, title 5, United States Code, and all other provisions of law related to rulemaking procedures.'"). Thus, the FDA could have implemented the new regulatory scheme immediately. Even so, the FDA waited. *Nine* months later, the FDA finally announced the Product Name Restriction, but gave only *three* more months before the regulation would take effect. If the FDA had acted promptly – even as late as September 2009 – there would have been time for this Court to have reached a final decision on the merits well before the regulation goes into effect on June 22, 2010, thereby avoiding the need for a preliminary injunction.

Moreover, even when the FDA made its March 2010 announcement of the Product Name Restriction, it did not do so unequivocally. Instead, it sent the unmistakable message that the agency knew the regulation was flawed and that it soon would be changed, so no one need worry. *See supra* at 10 (quoting 75 Fed. Reg. at 13226). More recently, the FDA posted on its website an additional signal that change was on its way. Apparently recognizing that the 1995 date for the "grandfather" clause is problematic, the FDA announced its intention to change that grandfather date to some unspecified, presumably later date. Exhibit A; *see also* discussion *supra* at 27-28 (explaining why a grandfather date earlier than 2010 or 2009 violates due process and is *ultra vires*). Yet, according to that website announcement, the official Notice of Proposed Rule-

Making ("NPRM") will not be published until *September* of this year, and the website gives no clue as to how much longer it will take the FDA to adopt a final rule amending the grandfather clause. In the meantime, the current regulation – with its irrational grandfather date of 1995 – will wipe out many of the new brands established over the last fifteen years. If the FDA had published its regulation promptly after Congress acted in June of 2009 – and if the agency were not so slow in addressing constitutional concerns about the regulation – there would have been time for these regulatory corrections to have been made without any court action. Having waited so late, and having published a regulation that is admittedly flawed, the FDA has no basis to object to a preliminary injunction preventing that regulation from going into effect next month.

C. The Equities Favor Protecting Plaintiffs' Constitutional Rights.

Additionally, the fact that it is the constitutional rights of Plaintiffs that are being violated by the regulation favors granting the injunction. As the Tenth Circuit Court of Appeals has held, "When the government fails to demonstrate its compelling interest in burdening a constitutional right, courts routinely find that, in the absence of a compelling justification for interference, the balance of harms and public interest also favor protecting the moving party's burdened rights." *O Centro Espirita*, 389 F.3d at 1027 (citing *Eisenberg v. Montgomery County Public Schools*, 197 F.3d 123, 127 n.11, 133 (4th Cir. 1999); *Stuart Circle Parish v. Bd. of Zoning Appeals*, 946 F. Supp. 1225, 1235-36, 1240 (E.D. Va. 1996)) (other citations omitted). Plaintiffs have established that the FDA lacks a compelling justification for interfering with their constitutional rights. *See* discussion *supra* at 15-18. Thus, this factor, too, weighs in Plaintiffs' favor.

D. The May 4, 2010 "Guidance" Issued by the FDA Tilts the Balance of the Equities Further in Plaintiffs' Favor.

In its May 4, 2010 Guidance, the FDA says that it will "exercise its enforcement discretion" by declining to "commence enforcement actions" for trade or brand names of

cigarettes and smokeless tobacco registered or marketed on or before June 22, 2009. Exhibit A. In offering this Guidance, the FDA has implicitly admitted that it does not believe the Product Name Restriction, as currently written, is constitutional. *See* discussion *supra* at 28-29 (citing *Stevens*, No. 08-769, 2010 U.S. LEXIS 3478 at *34-35). It would be absurd for the FDA to claim that it will be "harmed" if it is prevented from fully enforcing a regulation that the FDA now implies – albeit unconvincingly – it will not enforce as written.

In sum, considering traditional equitable factors as well as the relative harms to Plaintiffs and the government, the balance of the equities favors granting the injunction. The third prong of the *Winter* test has been satisfied.

III. The Public Interest Favors Granting an Injunction.

The final factor considered by courts in determining whether to issue an injunction is the public interest. The harm to the public interest would be great if the regulation is enforced, while enforcement of the regulation would provide little or no benefit to the public interest.

A. The Public Interest Would Be Harmed if the Regulation Is Enforced.

The preliminary injunction sought by Plaintiffs would promote the public interest for at least four reasons:

First, the preliminary injunction sought by Plaintiffs will preserve the status quo. Plaintiffs are not asking that they be allowed to do anything new. They are asking only that the Product Name Restriction not be enforced against brand names already trademarked and in use on March 19, 2010, the date the FDA announced its new regulation.[9]

[9] A preliminary injunction covering *all* such cigarette brands, regardless of the manufacturer, would certainly be in order; and the Plaintiffs ask the Court to grant such relief. In the alternative, the Plaintiffs ask that such relief be granted simply with respect *to their own* brands that were trademarked and in use as of March 19, 2010. These brand names are as
Footnote continues on next page.

Neither Renegade nor Seneca-Cayuga sells any non-tobacco product bearing the name of their brands, Tucson, Tracker, Barton or SkyDancer, and neither Renegade nor Seneca-Cayuga intends to do so. Mebane Decl. ¶ 5; Howard Decl. ¶ 6. Moreover, in order to assure the Court that the status quo will be preserved, Renegade and Seneca-Cayuga will readily agree *not* to sell any non-tobacco product bearing any of these names during the pendency of the preliminary injunction, and they have no objection to the Court's including such a restraint in this preliminary injunction. As the Fourth Circuit has recognized: the "*raison d'etre*" for a preliminary injunction "is to preserve the status quo during the course of a litigation in order to prevent irreparable injury to the moving party and in order to preserve the ability of the court to render complete relief." *Federal Leasing, Inc. v. Underwriters at Lloyd's*, 650 F.2d 495, 499 (4th Cir. 1981) (internal quotation omitted). Thus, the injunction sought by Plaintiffs is consistent with the purpose for which this Court has been granted the power to issue preliminary injunctions.

Second, an injunction will preserve competition and consumer choice, which are decidedly in the public interest. *See, e.g., Direx Israel, Ltd. v. Breakthrough Medical Corp*., 952 F.2d 802 (4th Cir. 1991) (recognizing "public interest in free competition in the marketplace"); *Lasercomb America, Inc. v. Reynolds*, 911 F.2d 970 (4th Cir. 1990) (same); *Signature Flight Support Corp. v. Landow Aviation Ltd. P'ship,* 2009 U.S. Dist. LEXIS 2541 at *35 (E.D. Va. Jan. 14, 2009) (holding that the public interest calls for "a diverse marketplace" with multiple sources of product from which to choose).

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follows: for Renegade – "Tucson," Serial No. 76156510, registered September 7, 2004; "Tracker," Serial No. 76525463, registered March 1, 2005; and "Barton," Serial No. 76547561, registered December 4, 2007; and for Seneca-Cayuga – "Skydancer," Serial No. 78172235, registered March 21, 2006, and "Golden Bay," for which Seneca-Cayuga serves as a contract manufacturer.

Without an injunction, the regulation will sharply reduce competition, consumer choice and diversity by forcing many existing products off the shelves. For example, in Virginia alone, there are 118 cigarette brands manufactured by 33 different small manufacturers (i.e., not one of the top four tobacco companies – Philip Morris, Reynolds American, Lorillard and Liggett) approved for sale. Virginia Tobacco Directory, Office of the Attorney General (April 2, 2009), available at http://www.oag.state.va.us/LEGAL_LEGIS/Tobacco/Tobacco_By_Brand.pdf. Of these brands, at least 77 did not exist as on January 1, 1995, and thus are ineligible for the 1995 Names-In-Use Exemption. *Id.* Many if not all of these 118 cigarette brands will become unlawful under the regulation, either because another non-tobacco product was not being manufactured on January 1, 1995 (for the 41 brands that existed at that time), or because someone, somewhere in the national economy uses the same name on a non-tobacco product (for the other 77 brands).

Moreover, it is not just a question of product taste. It is also a question of price. The newer brands are typically cheaper than the major brands. For example, the six most popular major brands currently sell at wholesale in the range of $27.81 to $33.60 per carton, Mebane Decl. ¶ 18, see also Howard Decl. ¶ 12, while minor brands, such as Renegade's wholesale for about $18.50 and $21.50 per carton, Mebane Decl. ¶ 17, and Skydancer wholesales for about $13.09 to $15.07 per carton, Howard Decl. ¶ 12. As the Product Name Restriction forces the newer brands from the shelves, retailers will be forced to turn to the more expensive, major brands, and in turn, so will consumers. Such a drain of consumer income is not in the public interest.

Third, the regulation would not only eliminate diversity in the marketplace, it would do so by restricting commercial speech, thereby greatly magnifying the public interest in a

preliminary injunction. *E.g., Ctr. for Individual Freedom, Inc. v. Ireland*, 613 F. Supp. 2d 777, 807-08 (S.D. W. Va. 2009) ("Obviously, the protection of First Amendment rights is very much in the public's interest.").

Fourth, the Product Name Restriction would not only force many existing products off the shelves, it would force out of business many small manufacturers whose soon-to-be prohibited brands are the mainstay of their economic livelihood. The result would be felt not only by the manufacturers, but by their employees who would lose their jobs and their creditors who would go unpaid. The Plaintiffs in this case furnish salient examples of these ripple effects.

Renegade: Renegade has 144 employees and has an annual payroll of approximately $5.4 million, including payroll taxes, health insurance and other benefits. If Renegade is forced to close its doors, the loss of jobs will have a detrimental impact on these employees and their families. Mebane Decl. ¶ 24. If Renegade is forced to close its doors, this also will have major ripple effects on other companies. Renegade will be unable to pay its creditors, including banks, suppliers, vendors, etc. *Id.* ¶ 23. The regional economy will suffer, too, if Renegade is forced to shut down operations. Renegade is headquartered in the Town of Mocksville, in Davie County, North Carolina. In a letter dated March 15, 2010, Terry Bralley, President of the Davie County Economic Development Association explained that Renegade's closure would result in a total of 734 jobs lost regionally (including direct job losses and "spin off" job losses), and a loss of over $17 million annually from the local economy. *Id.* ¶ 35 & Exhibit F. This result would be disastrous for Davie County, which has a 12.8 percent unemployment rate. Mebane Decl. ¶ 35.

Seneca- Cayuga: The Seneca-Cayuga Tribe of Oklahoma manufactures cigarettes on its reservation lands near Grove, Oklahoma, in the sparsely-developed northeast corner of the State. Howard Decl. ¶ 4. During the first two quarters of our 2010 fiscal year (beginning October 1,

2009), Seneca-Cayuga's cigarette sales in the U.S. market totaled $31,018,281. Out of this sum, it paid $24,512,090 in excise taxes. Seneca-Cayuga's gross sales for the last fiscal year (October 1, 2008 – September 30, 2009) totaled $51,122,195. Out of this sum, it paid $41,347,783 in excise taxes. *Id.* ¶ 10.

Seneca-Cayuga has 67 employees, approximately 85 percent of whom are either members of the Tribe or spouses of tribal members. Seneca-Cayuga has an annual payroll of approximately $2.5 million, including payroll taxes, health insurance and other benefits. If Seneca-Cayuga is forced to close its doors, the loss of jobs will have a detrimental impact on these employees and their families. *Id.*. ¶ 19.

If Seneca-Cayuga is forced to close its doors, this will also have ripple effects on other companies and on the surrounding community. First, Seneca-Cayuga will be unable to pay its creditors, including banks, suppliers, vendors, etc. *Id.*. ¶ 18. Second, the closure of Seneca-Cayuga will have a detrimental impact on the Tribe which has historically experienced a higher unemployment rate than the surrounding area. The loss of the 67 jobs at Seneca-Cayuga likely will have a ripple effect and cause the loss of other jobs in the area, including jobs held by other tribal members and non-members. *Id.*. ¶ 20.

B. Enforcement of the Regulation Would Provide No Benefit to the Public Interest.

While the public interest clearly would be harmed by enforcing the Product Name Restriction against Plaintiffs, the harm to the public if the regulation is not enforced is non-existentl. The FDA's stated rationale for imposing the regulation – namely, that the Product Name Restriction will reduce youth smoking – rings hollow. The regulation is designed to *protect* the major brands by giving them the benefit of the 1995 Names-In-Use Exemption, but it

is the *major* brands – *not* the newer, lower tier brands – that young smokers typically choose. *See supra* at 17-18.

C. The FDA's May 4, 2010 "Guidance" Shows that the Public Interest Favors Issuing the Injunction.

With its May 4 "Guidance," the FDA offers protection to small tobacco manufacturers with one hand while, with the other hand, it takes this protection away. By its plain terms, the "Guidance" confers no rights on anyone, leaves enforcement entirely up to the FDA's discretion, provides for exercise of such discretion only during the duration of the reconsideration of the regulation (a period of unknown duration) and reserves the right at any time to begin enforcing the regulation as originally written. The public interest disfavors such a recipe for arbitrary enforcement. As the Supreme Court has stated, "the First Amendment protects against the Government; it does not leave us at the mercy of *noblesse oblige*." *Stevens*, 2010 U.S. LEXIS 3478, at *35. The public has an interest in knowing the law and how it will be interpreted and enforced. Otherwise, the public will be left to the whims of a capricious government. The public interest therefore favors issuing the injunction.

CONCLUSION

Plaintiffs have established that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest.

RENEGADE TOBACCO COMPANY, INC., ALTERNATIVE BRANDS, INC., RENEGADE HOLDINGS, INC., and SENECA-CAYUGA TOBACCO COMPANY

By /s/
Stephen C. Piepgrass (VSB No. 71361)
Of Counsel

William H. Hurd (VSB No. 16769)
william.hurd@troutmansanders.com
Anthony F. Troy (VSB No. 05985)
tony.troy@troutmansanders.com
Ashley L. Taylor, Jr. (VSB No. 36521)
ashley.taylor@troutmansanders.com
Bryan M. Haynes (VSB No. 42848)
bryan.haynes@troutmansanders.com
Stephen C. Piepgrass (VSB No. 71361)
stephen.piepgrass@troutmansanders.com
TROUTMAN SANDERS LLP
1001 Haxall Point
P.O. Box 1122
Richmond, Virginia 23219
(804) 697-1200 (phone)
(804) 698-5147 (fax)

CERTIFICATE OF SERVICE

I hereby certify that the foregoing was filed electronically with the Clerk of the Court, using the CM/ECF system, which sent notification of such filing to the following counsel for U.S. Food and Drug Administration and Margaret Hamburg, M.D., Commissioner of Food and Drugs, this 6th day of April, 2010:

Debra J. Prillaman, Esquire
Debra.Prillaman@usdoj.gov
Assistant United States Attorney
600 East Main Street, Suite 1800
Richmond, Virginia 23219
Telephone: (804) 819-5400
Facsimile: (804) 819-7417

/s/
Stephen C. Piepgrass (VSB No. 71361)
stephen.piepgrass@troutmansanders.com
TROUTMAN SANDERS LLP
1001 Haxall Point
P.O. Box 1122
Richmond, Virginia 23219
(804) 697-1200 (phone)
(804) 698-5147 (fax)

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